UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,260	07/12/2000	KENGO AKIMOTO	001560-381	7267

7590 06/10/2003

RONALD L GRUDZIECKI
BURNS DOANE SWECKER & MATHIS
PO BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/10/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,260	AKIMOTO ET AL.	
	Examin r	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-11, 13-17,19-20 and 23-37* is/are pending in the application.

4a) Of the above claim(s) *1-10,13-16 and 23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,17,19,20 and 27-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/27/03 has been entered.

Claims 11, 17, 19-20, and 27-37 are being considered on the merits.

Claims 12, 18, 21 and 22 are cancelled. Claims 1-10, 13-16, and 23-26 are withdrawn from consideration as directed to a non-elected invention.

. To conform with standard practice and for the sake of clarity, independent claims should be amended to start with --The-- and dependent claims to start with --A--.

As noted in the advisory action, claim 21 is cancelled and amended at the same time. A cancelled claim cannot be amended.

Claims 11, 17, 19-20, and 27-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and inconsistent in the recitation of "arachidonic acid **to** the total fatty acids in said lipid is..." in claim 11; "arachidonic acid content **in** the total fatty acids in the lipid is..." in claim; and "arachidonic acid content **per** the total fatty acid in the lipid is..." in claims 21 (cancelled) and claim 27. The distinction, if any, intended is unclear.

Claims 11, 17 and 27 are vague and indefinite in the recitation of "obtainable" with respect to the lipid, since it is unclear under which circumstances it is or it is not "obtainable".

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to applicant's arguments, it is noted that "arachidonic acid to the total fatty acids in the lipid is..." is not claim language used consistently.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12, 17-22 and 27-37 are/remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Totani *et al.*.

The claims are drawn to a microbial lipid containing arachidonic acid at levels higher than 50% or 70% and eicosapentaenoic acid of less than 0.5%.

The cited reference discloses a microbial lipid containing arachidonic acid which appears to be identical to the presently claimed microbial lipid containing arachidonic acid since the lipid from *Mortierella* has been purified to contain 99% arachidonic acid (See, e.g., page 59, paragraph 2). The referenced microbial lipid containing arachidonic acid appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class as that of the microbial lipid claimed, it shares substantially the same origin and contains substantially the same amount of arachidonic acid and eicosapentaenoic as claimed. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed microbial lipid is not identical to the referenced microbial lipid, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microbial lipid is likely to possess the same characteristics of the claimed microbial lipid particularly in view of the similar characteristics which they have been shown to share. Thus the claimed microbial lipid would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 11-12, 17-22 and 27-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li *et al.*.

The claims are drawn to a microbial lipid containing arachidonic acid at levels higher than 50% or 70% and eicosapentaenoic acid of less than 0.5%.

The cited reference discloses a microbial lipid containing arachidonic acid which appears to be identical to the presently claimed microbial lipid containing arachidonic acid enzyme. since the lipid from *Mortierella* contains 72.5% arachidonic acid (See, e.g., page 138, first full paragraph and Table 6), and the amount of eicospentaenoic acid indicated as being 1.01% appears to be within experimental error of the amount as claimed.

The referenced microbial lipid containing arachidonic acid appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class as that of the microbial lipid claimed, it shares substantially the same origin and contains substantially the same amount of arachidonic acid as claimed. Even though the amount of eicospentaenoic acid is indicated as being 1.01%, this value is deemed to be within experimental error of the amount required. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed microbial lipid is not identical to the referenced microbial lipid, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microbial lipid is likely to possess the same characteristics of the claimed microbial lipid particularly in view of the similar characteristics which they have been shown to share. Thus the claimed microbial lipid would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the lipid of the invention is characterized as having a high content of arachidonic and a low content of eicosapentaenoic acid. It is submitted that the lipid disclosed by the references substantially meets the claimed invention. The invention as claimed does not pertain to a lipid that is produced is a certain way, since there are no method claims under examination. In product by process claims, the claims are examined in terms of the product and not in terms of the process used to obtain the product. In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985). It is noted that the arachidonic acid in Totani *et al.* is 99% arachidonic acid (See, e.g., page 59, paragraph 2).

With respect to Li *et al.*, the results at page 138, Table 6 suggest that the content of eicosapentaenoic acid is very low, and is not apparent that the composition disclosed in the reference is patentably distinct from the composition as claimed.

Therefore the rejection is deemed proper and it is adhered to.

As indicated previously, one or more independent claim(s) such as written below would distinguish over the art:

--An organic solvent extract of a fungal biomass, wherein the fungus lacks ω-3 desaturase activity or has decreased ω-3 desaturase activity, and wherein the fungal biomass comprises arachidonic acid in an amount of 72% or more (respectively 50% or more) by weight to the total fatty acids in said lipid and eicosapentaenoic acid in an amount of less than 0.5% by weight to the total fatty acids in said lipid. --

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx

Irene Marx
Primary Examiner
Art Unit 1651